

REMARKS

The withdrawal of the previous grounds of rejection under 35 U.S.C. § 112, 2nd paragraph and 35 U.S.C. § 103(a) is gratefully acknowledged.

With this amendment, claims 35 and 43 have been amended to improve clarity. Support for replacement of "forming" with "precipitating" in the first step of claim 35 is found in the present specification at paragraphs 0023 and 0152. Accordingly, the amendments do not constitute the addition of new matter. Support for addition of ethanol/methanol in the 4th step is found in cancelled claims 41-42. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 103(a)

Claims 35-37 and 39-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Merck (DE 3405663), in view of Weser (Structure and Bonding, vol. 2: 160-180, 1967) and in view of Weissbach (Journal of Organic Chemistry 23: 329, 1958) and Sigma-Aldrich (Technical Information Bulletin AL-142).

Merck (DE 3405663) discloses a method of obtaining scyllo-inositol. However, the technical means for obtaining scyllo-inositol are totally different from the method of the present invention. In order to further distinguish the claimed invention from Merck, claim 35 has been amended to replace "forming" with "precipitating". Support is found in the present specification at paragraphs 0023 and 0152.

As understood from the computer-generated English translation and English Abstract, Merck discloses a method of obtaining scyllo-inositol comprising the steps of oxidizing myo-inositol with a platinum catalyst to thereby obtain myo inosose (also called scyllo-inosose) and subjecting the myo inosose to esterification followed by reduction and azeotropy.

As can be understood from the partial English translation of Merck (page 2, paragraph 12) submitted herewith as Attachment, boric acid is formed when the esterified myo inosose (myo-inosose pentaacetate) is reduced with sodium borohydride. By removing boric acid with azeotropy, purified scyllo-inositol is obtained. Merck discloses that the reaction mixture is made acidic with 2N hydrochloric acid and methanol is repeatedly added therein, followed by

azeotropy (evaporation) to thereby remove boric acid together with acetic acid that is derived from the protection group of myo inosose.

That is, Merck isolated scyllo-inositol from the reaction mixture obtained by reducing esterified myo inosose with sodium borohydride, by removing boric acid with azeotropy. Merck does not disclose the formation of a scyllo-inositol/boric acid complex by adding boric acid and a metal salt.

The Examiner stated that borate is generated *in situ* by the addition of sodium borohydride with is equivalent to the addition of boric acid to the basic reaction mixture (Office Action, page 9, paragraph 1). However, one of ordinary skill in the art would not expect that scyllo-inositol/boric acid complex is formed during these procedures because the reduction reaction was performed in methanol in the method of Merck (see Attachment with translation of page 2, paragraph 12). Applicants believe that Merck does not disclose the formation of scyllo-inositol/boric acid complex.

Moreover, it should be noted that the step of separating the scyllo-inositol/ boric acid complex (second step in claim 35) is not disclosed anywhere in Merck.

Merck further differs from the claimed invention in addition of methanol to remove boric acid with azeotropy, not precipitation of scyllo-inositol as claimed. This limitation has now been incorporated into claim 35. Support is found in cancelled claims 41-42. Further, the amount of methanol added in Merck is 10 times the volume of the reaction mixture (see the English translation) which is different from the volume of the present invention (0.3 to 5 times).

Wesser discloses that borate forms chelate complex with sugars, but this chelate reaction is an equilibrated reaction as shown in formula (a) of page 165 and not a strong interaction so that a skilled artisan will understand that the chelate complex is soluble in aqueous solution. That is, Wesser never discloses that the complex of borate and sugar precipitates.

The Examiner cited Wesser as teaching formation of the boric acid complex for the purpose of separating a mixture of carbohydrates. However, the Examiner omitted the phrase "when subjected to ion exchange chromatography" as described on page 171, second paragraph. That is, Wesser means that the complex dissolved in a solution can be separated by ion exchange

column chromatography, which clearly shows that Wesser does not disclose that the chelate complex precipitates.

Furthermore, Wesser neither discloses nor suggests the relationship between the complex formation and metal salt. Although the Examiner cited Wesser as teaching formation of the boric complex depends on the apparent ionization constant of boric acid (page 165, paragraph 5), it should be noted that Wesser teaches "Kn' are apparently independent of the ionic strength" in the same paragraph. Kn' is the chelation reaction constant as defined in formula (c). As disclosed formula (d) and Fig. 8 of Wesser, the chelation reaction constant depends on the concentration of sugar but not metal salt.

The Examiner also cited Wesser as teaching that formation of the boric complex with a saccharide or sugar alcohol is performed in KCl salt solution (page 166, Table 1). However, KCl salt is added to perform potentiometry (note that the title of the chapter starting from the second paragraph of page 165 is "Potentiometry"), not precipitation of a scyllo-inositol/boric acid complex.

The Examiner also cited page 171, Fig. 10 of Wesser as teaching the formation of the boric polyol complex in the presence of a NaCl salt concentration. However, NaCl is added to elute nucleosides attached to the column in the ion exchange column chromatography, not precipitation of a scyllo-inositol/boric acid complex.

That is, Wesser's disclosure on metal salt is not in the context of formation of a scyllo-inositol/boric acid complex. Wesser neither discloses nor suggests the relationship between complex formation and metal salt.

Weissbach disclose the formation of the scyllo-inositol/boric acid complex and isolation of the complex as a precipitate. However, Weissbach does not disclose the addition of metal salt. Furthermore, Weissbach uses a mixture of strongly acidic and strongly basis resins for isolation of scyllo-inositol from the complex. In contrast, in the method of the present invention, methanol is added to precipitated scyllo-inositol, which is neither disclosed nor suggested in Weissbach. Accordingly, Weissbach teaches away from the claimed invention.

As mentioned above, Merck relates to a technology totally different from the method of the present invention and does not disclose the formation of scyllo-inositol/boric acid complex. Combining Merck with Wesser and Weissbach does not lead to the claimed invention.

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Furthermore, neither Wesser nor Weissbach teach the relationship between complex formation and metal salt. Accordingly, the secondary references do not correct the deficiencies of Merck and do not teach the claimed invention when combined.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Translation of German reference

Merk . paragraph 12

DE 2405663

Scyllo-inositol:

The solution of 0.75 g of sodium borohydride in 125 ml of absolute methanol is added dropwise, while stirring at room temperature, to a suspension of 5.0 g of myo-inosose pentaacetate in 125 ml of absolute methanol and the whole is stirred for a further 30 minutes at room temperature. The solution is acidified with 2N hydrochloric acid and concentrated to 20 ml. In order to separate off the borate, 200 ml of methanol are added and distilled off several more times. The whole is then concentrated to dryness by evaporation, the residue is dissolved in 30-50 ml of water, and the solution is filtered over a cation exchange column (100 g Levatit SC 102 H) and then washed with water until the filtrate reacts in a neutral manner. The aqueous solution is concentrated to approximately 20 ml, 200-250 ml of methanol are added and the whole is refrigerated.

The scyllo-inositol, which is precipitated in the form of fine, colourless crystals, is filtered off with suction and then washed with methanol.

Yield: 1.6-1.8 g, m.p.: 345-347°C.

By concentrating the mother liquor, a second, less pure, crystallisate can be obtained.